IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Legerton et al.	) Group Art Unit 2873
Appl. No.	:	10/657,061	)
Filed	:	September 5, 2003	)
For	:	HYBRID CONTACT LENS SYSTEM AND METHOD	)
Examiner	:	Jessica T. Stultz	)

DECLARATION OF WILLIAM E. MEYERS PURSUANT TO 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, William E. Meyers, declare and state as follows:

1. I am a United States citizen and I reside at 12427 North 129th Place, Scottsdale, AZ 85259.

2. I am currently Vice President of Science and Technology at Paragon Vision Sciences, 947 E. Impala Avenue, Mesa, AZ 85204. I have held this position for 9 years. My duties include research and development of new materials for contact lenses and regulatory affairs and quality control. Prior to this, I worked as a consultant to Rasor Associates, Inc. and Specialty Ultravision for about seven months, where my duties included consulting regarding the development of a contact lens design. While consulting with Rasor Associates, I worked on the development of a contact lens involving a combination of polymers. This lens was sold commercially under the name Epicon, but it was not a hybrid lens. Prior to this consulting position, I was Vice President of Research and Development at Pilkington Barnes Hind for 7 years, where my duties included research and development for contact lens materials and lens care products. Prior to this, I was Vice President of Research and Development at Syntex Ophthalmics for 5 years, where my duties included development of new materials and manufacturing processes for contact

lenses. Prior to this, I was a Division Head for the Biotechnology Division at the Southern Research Institute for 6 years, where my duties included research with respect to polymers. I have worked in the contact lens industry for the past 21 years.

3. I have a Doctorate in Biochemistry from Ohio State University, which I obtained in 1978. My thesis was regarding the use of synthetic polymers to mimic the activity of biopolymers. I also hold a Bachelor of Science in Biochemistry from Ohio State University, which I obtained in 1973.

4. I was a member and served as an editor of the national publication published by the Controlled Release Society. This organization dealt with the release of pharmaceuticals through polymers. I am a member of the Contact Lens Association of Ophthalmology (CLAO), which publishes a journal ("The Eye and Contact Lenses"). I read this journal regularly. I was on the guiding board for a Material Sciences Symposium held regularly in New Orleans, Louisiana. I attend this symposium regularly and have been a past presenter. I also participate in meetings of the International Society for Contact Lens Research (ISCLR).

5. I am a named inventor on several patents and patent applications, several of which are in the contact lens field. In addition, I have authored numerous publications and technical reports and made numerous technical presentations, many of which involve contact lenses and/or contact lens material science.

6. I currently serve as a consultant with SynergEyes, Inc, previously Quarter Lambda Technologies, Inc., the owner of the pending patent application. I am assisting SynergEyes, Inc. on the development of a hybrid contact lens. I do not hold stock or any ownership interest in SynergEyes, Inc.

7. I have worked in the contact lens industry for the past 21 years, including the research and development of polymers used in the manufacture of contact lenses. Further, I've been involved in research related to materials for rigid and soft contact lenses and their compatibility with the human eye. I have also worked with hybrid contact lenses. While at Barnes Hind around 1988-89, I became involved with hybrid contact lenses, including performing research and development. The hybrid contact lens, called the Saturn lens, had a soft hydrophilic peripheral skirt, and we experienced bonding problems, including the delamination of the contact lens at the junction. The commercially available Saturn hybrid contact lens had a low Dk center and low Dk

skirt. I understand that the major problem with the Saturn lens is that it delaminated at the junction. The Softperm contact lens, which incorporated a change in the geometric shape of the Saturn lens, and which is currently commercially available, also has a low Dk center and a low Dk peripheral skirt. It is my understanding that the Softperm lens continues to have tearing problems.

8. I have reviewed the pending claims in the above-identified application and the proposed amendment to the claims filed herewith. I have also reviewed U.S. Patent No. 6,043,328 ("Domschke") and GB Patent No. 1,417,650 ("Sohnges"), the two references I understand the Examiner has used to reject pending claims in the above-identified application as being obvious. I disagree that these claims are obvious in view of Domschke and Sohnges.

9. In my opinion, the combination of Domschke and Sohnges would not render the pending claims obvious to one of ordinary skill in the art for at least the following reasons:

10. Domschke does not disclose, teach or suggest a hybrid contact lens with a substantially rigid central portion having a Dk of at least 30×10^{-11} (cm^2/sec) (mL O_2)/ (mL x mm Hg) and substantially flexible hydrophilic peripheral or annular portion coupled to the substantially rigid central portion at a junction defined at an outer edge of the substantially rigid central portion. Instead, Domschke describes a polysiloxane-polyol macromer material, and contact lenses including said material. Domschke also discloses coating a surface of a lens with a hydrophilic material to improve the hydrophilicity of the lens. Indeed, there is no disclosure or suggestion in Domschke to provide a hydrophilic peripheral skirt, or bond a hydrophilic peripheral skirt to a rigid central portion. Domschke's single reference to a hybrid lens appears to refer to either (a) a lens with a rigid core section and a hydrophilic surface, (b) a rigid gas permeable lens with very high flexure, or (c) a soft lens made of a Silicon Elastomer (aka Silicon rubber) with no water content, all of which have been referred to at times in the contact lens industry as hybrid lenses because they exhibited some characteristics found in both soft and rigid gas permeable lenses (e.g., intermediate rigidity between that of an rigid gas permeable lens and that of a soft lens). However, none of these contact lenses (i.e., a lens with a rigid core section and a hydrophilic surface, a rigid gas permeable lens with very high flexure, or a soft lens with no water content) teach or suggest a contact lens having a substantially rigid central portion coupled to a substantially flexible hydrophilic peripheral portion, as recited in the amended claims of the above-identified application.

11. With respect to Sohnges, the reference does not disclose a hybrid contact having a hard central portion with a Dk of at least $30x10^{-11}$. In fact, this patent does not even disclose an oxygen permeable rigid lens material. To the contrary, it discloses attempting to deliver oxygen to the eye through tear pumping or movement under the lens. Further, Sohnges discloses microlenses, which are smaller than the diameter of a human cornea. If the lens of Sohnges was larger so as to serve the purpose of a hybrid contact lens, the lens would be too large to permit tear pumping or movement under the lens and would starve the cornea of oxygen. Moreover, Sohnges teaches away from using a hydrophilic skirt, and the materials identified in Sohnges are not hydrophilic. Indeed, there is no disclosure or suggestion in Sohnges to 1) provide a high Dk central portion, 2) provide a hydrophilic skirt, or 3) bonding a high Dk central portion to a hydrophilic skirt in any manner. Therefore, one of skill in the art looking at these two references would not be able to combine the material in Domschke with the lens in Sohnges to obtain the claimed invention.

12. In order to provide a comfortable lens, it is important that the lens be wide enough to cover at least the cornea, which prevents the lens from excessive movement and eyelid interaction. With respect to hard contact lenses, although they provide superior vision, movement of the lens occurred often, causing discomfort with every blink. Further, foreign objects are free to migrate under the hard lens with tear exchange, causing pain and corneal trauma. With soft lenses, it is possible to manufacture a wider lens, which experiences less movement in the eye and less movement caused by eyelid interaction, resulting in less discomfort, and foreign bodies are prevented from migrating under the lens. However, soft lenses do not provide the visual quality of the rigid optics of a hard lens.

13. Therefore, there has been a long-felt need in the industry for a hybrid contact lens having a hard central portion with a high Dk providing high quality vision and high oxygen permeability and a soft peripheral skirt providing greater comfort, as described above. I am aware since at least as early as 1988 of attempts that have been made to manufacture an improved hybrid contact lens. To the best of my knowledge, none of these efforts ever succeeded resulting in a commercial product.

14. In view of the long-standing efforts by others, and my knowledge of the contact lens industry over the past twenty-one years, I do not believe the claimed invention recited in the

pending claims of the above-identified application are obvious in view of Domschke and Sohnges.

15. I declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-identified application and any patents issuing thereon.

Dated: JAN 20, 2006

William E. Meyers, PhD

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